

Medtronic

Symplicity Spyral™
renal denervation system

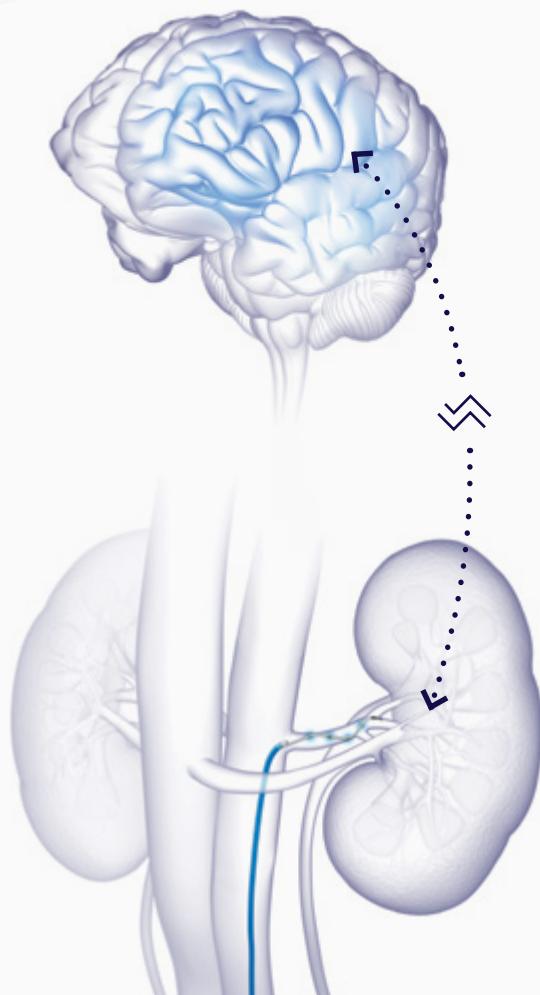
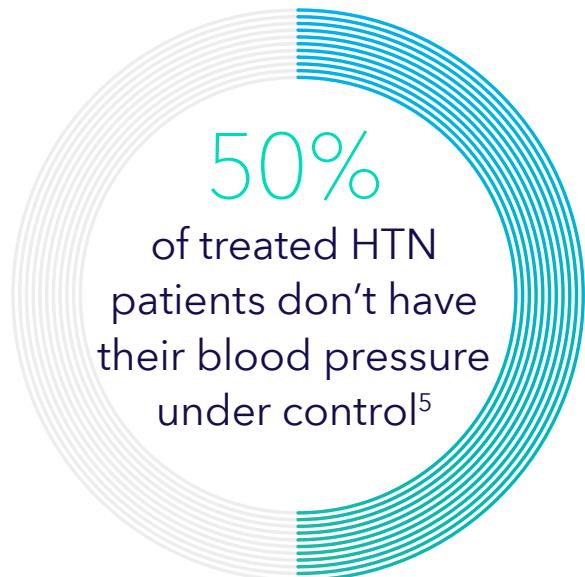
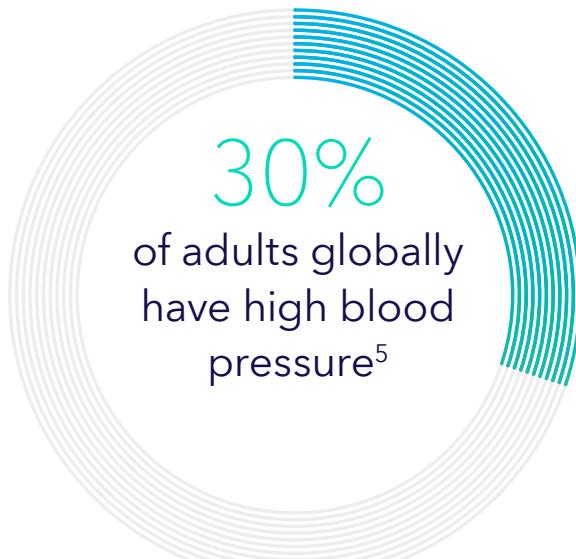


Setting the
standard
in renal denervation

The Symplicity™ blood pressure procedure delivers
significant, safe, and sustained BP reductions.¹⁻⁴

When typical hypertension treatments aren't enough

Lifestyle changes and medications have defined hypertension treatment, but they are not always enough to help patients achieve control.



How renal denervation with Symplicity Spyral works:

- The kidneys modulate the sympathetic tone via the renal nerves to control blood pressure
- Symplicity Spyral supplies precisely controlled and targeted radiofrequency energy to the renal nerves⁶
- The procedure safely disrupts the overactive sympathetic signaling between the kidneys and brain, to reduce blood pressure⁶

Turn to an approach recommended by societies

- The **European Society of Hypertension (ESH) guidelines** now recommend RDN as a safe and effective complementary hypertension treatment strategy⁷
- The **ESC-EAPCI* consensus statement** also recommends renal denervation and recognises it as a complementary treatment strategy, adjunctive to lifestyle and pharmacological interventions⁸

ESH 2023 Guidelines: Patient selection criteria⁷

Uncontrolled BP



Patients with an eGFR>40ml/min/1.73m² who have **uncontrolled BP** despite the use of **antihypertensive drug combination therapy**, or if drug treatment elicits **serious side effects** and poor quality of life.

Resistant Hypertension



Patients with resistant hypertension if eGFR>40ml/min/1.73m²

ESH additional recommendations⁷



Selection of patients should be done in a **shared decision-making process** after objective and complete patient's information.



Performed in experienced specialised centres to guarantee **appropriate selection of eligible patients** and completeness of the denervation procedure.



Setting the standard in renal denervation

>25,000

patients treated globally with
the Symplicity RDN system⁹

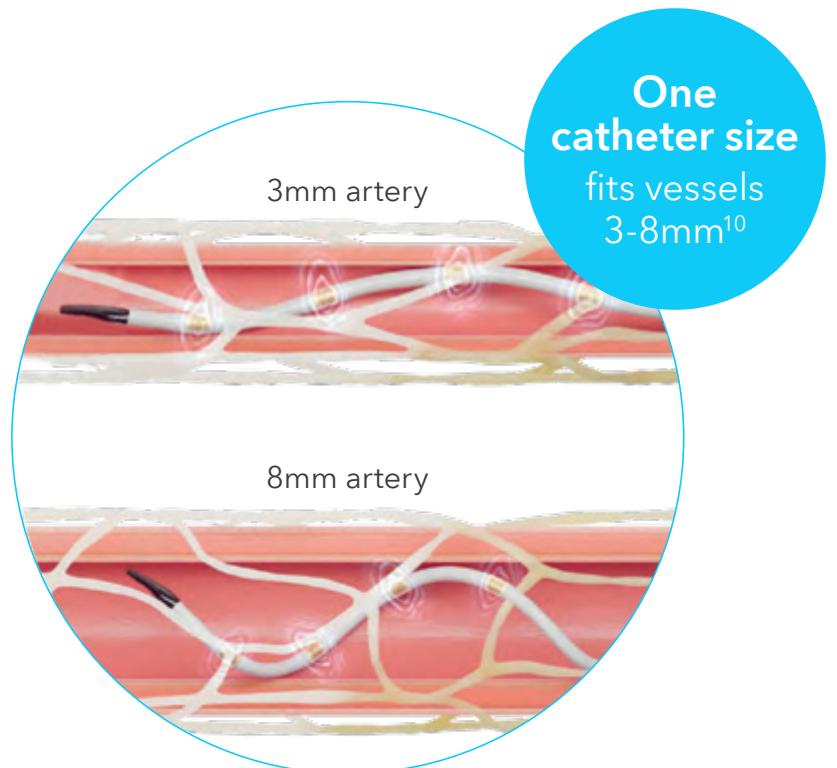
The Symplicity™ blood pressure procedure is a simple, minimally-invasive approach to achieve BP reductions, independent of patient adherence. Precisely controlled and targeted **radiofrequency (RF) energy** is delivered to the renal nerves⁶ with no permanent implant left behind.

Symplicity Spyral™
Multi-Electrode Renal
Denervation Catheter

- 4 F catheter,[†] compatible with 6 F guide catheter, 0.014" guidewire
- Four independently controlled electrodes
- Shaped atraumatic tip with radiopaque marker

Simple and versatile

- One catheter size fits vessels 3-8mm¹⁰
- Easy-to-use, **plug-and-play** design
- **Nonocclusive design** allows for continuous blood flow to naturally protect the vessel wall⁶



Safe and precise

Safe

- Radiofrequency energy preferentially heats fat tissue where renal nerves are located and **avoids non-target structures**¹¹
- Unique, real-time and **responsive algorithm** automatically adjusts power by monitoring temperature and impedance for safe energy distribution⁶

Symplicity G3™ Renal Denervation RF Generator

Precise ablation

- Multi-electrode, helical design covers four quadrants simultaneously for a circumferential ablation^{6,10}
- Only Symplicity Spyral™ allows for denervation throughout the renal anatomy, including the distal branches,¹⁰ where late arriving nerves are accessible and total nerve density is highest^{12,13}



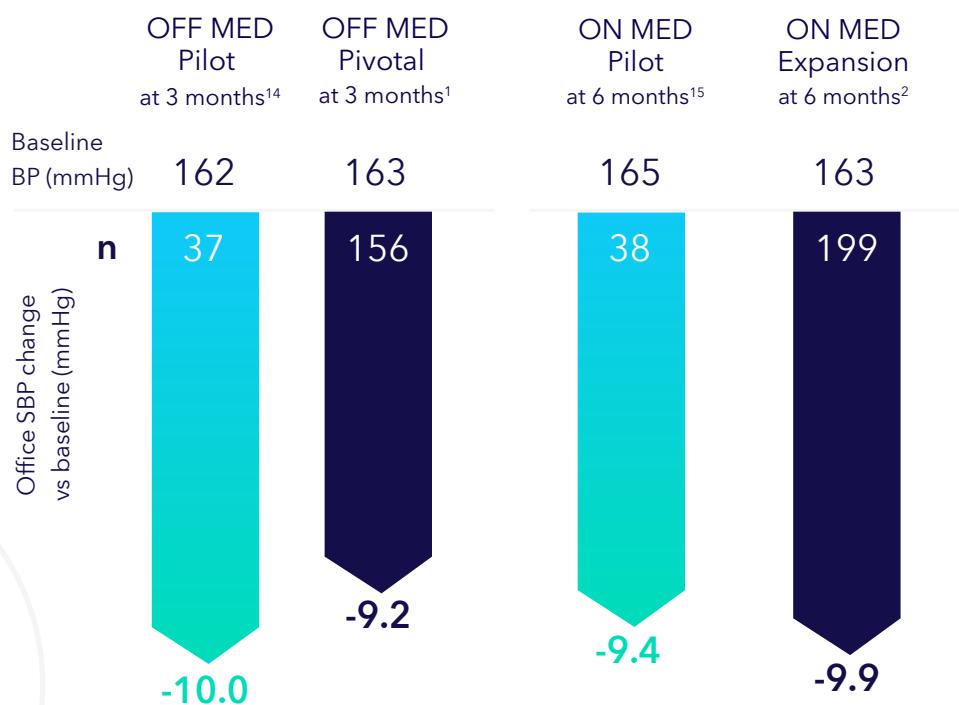
Significant, safe, and sustained blood pressure reductions¹⁻⁴

Supported by clinical evidence **unmatched** in scope,
quantity and quality.

>4,000 patients enrolled in the
global clinical program^{‡1-3,14,15,17}

Significant

Consistent blood pressure reductions in 4 sham-controlled trials,
in both the presence and absence of medications^{1,2,14,15}



9
mmHg

OSBP reduction in
patients off and on
medications^{1,2,14,15}

Safe

Excellent safety profile^{1,2}

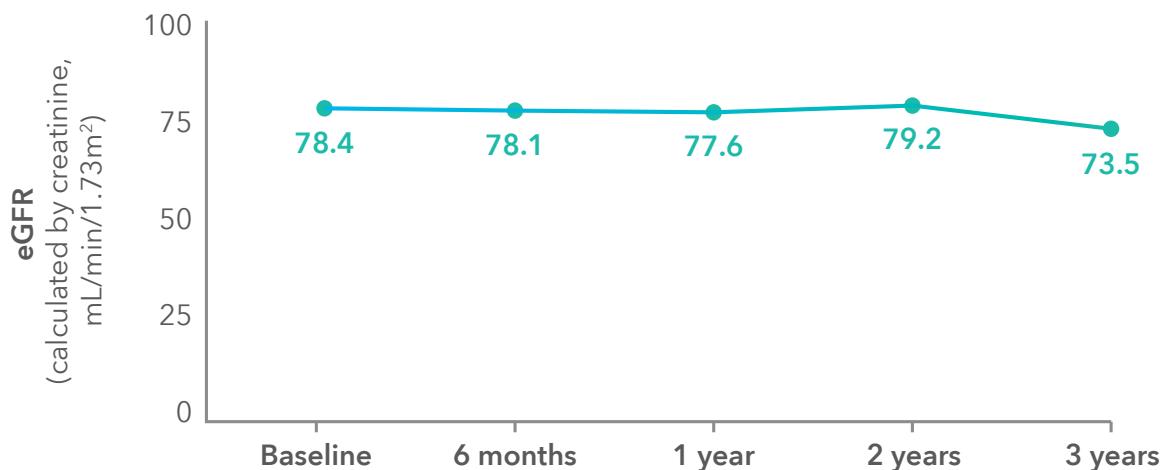
Pooled data indicated low incidence of procedural and clinical adverse events²

0.4%

major adverse event rate at composite endpoint, including no new incidence of renal artery stenosis (>70%) at 6 months²

Stable kidney function

Minimal impact to kidney function at 3-year follow-up¹⁶



Sustained

Only renal denervation with Symplicity Spyral™ System has demonstrated lasting blood pressure reductions **at 3 years**.¹⁷

18
mmHg

reduction in OSBP at 3 years. n=267¹⁷



RDN016 Symplicity Spyral multi-electrode renal denervation catheter: single-use RDN catheter for use only with the Symplicity G3 renal denervation RF generator

RDNG3A/RDN017 (as approved in your country) Symplicity G3 generator: reusable RF generator, power cable, remote control, and DVI-D output for use with the Symplicity Spyral catheter

RDN019 Mobile cart for Symplicity G3 generator (optional accessory)

Guidewire: 0.014" non-hydrophilic guidewire with a supportive shaft and a floppy tip

Guide catheter: 6 F guide catheter (90 cm max length)

Recommended models:

SB6RDND1K - Sherpa NX™ Balanced 6Fr 55-cm guide catheter with RDND1 curve

LA6RDCK - Launcher™ 6Fr 55-cm guide catheter with RDC curve

LA6IMAK - Launcher™ 6Fr 55-cm guide catheter with IMA curve

SB6IMAK - Sherpa NX™ Balanced 6Fr 55-cm guide catheter with IMA curve

Dispersive Electrode for RDNG3A: Compatible with ValleyLab REM Polyhesive Adult Patient Return Electrode (Model **E7507, E7507-DB**)

Dispersive Electrode for RDN017: A disposable dispersive electrode with a molded connector specified for adult use that complies with IEC 60601-2-2 is required

*European Society of Cardiology (ESC) Council on Hypertension and European Association of Percutaneous Cardiovascular Interventions (EAPCI)

¹Catheter dimension of 0.052" is average diameter determined during design verification. Upper bound allowable is 0.061".

²Study follow-up is ongoing. Data does not represent follow-up for all patients.

³Not all subjects analyzed have completed follow-up through 3 years. All available data included at the time of this analysis.

¹Böhm M, Kario K, Kandzari DE, et al. Efficacy of catheter-based renal denervation in the absence of antihypertensive medications (SPYRAL HTN-OFF MED Pivotal): a multicentre, randomised, sham-controlled trial. *Lancet*. May 2, 2020;395(10234):1444-1451.

²Kandzari DE, Townsend RR, Kario K, et al. Safety and Efficacy of Renal Denervation in Patients Taking Antihypertensive Medications. *J Am Coll Cardiol*. 2023;82(19):1809-1823

³Mahfoud F, Mancia G, Schmieder RE, et al. Outcomes Following Radiofrequency Renal Denervation According to Antihypertensive Medications: Subgroup Analysis of the Global SYMPPLICITY Registry DEFINE. *Hypertension*. 2023;80(8):1759-1770

⁴Mahfoud F, Kandzari DE, Kario K, et al. Long-term efficacy and safety of renal denervation in the presence of antihypertensive drugs (SPYRAL HTN-ON MED): a randomised, sham-controlled trial. *Lancet*. April 9, 2022;399(10333):1401-1410.

⁵NCD Risk Factor Collaboration (NCD-RisC). Worldwide trends in hypertension prevalence and progress in treatment and control from 1990 to 2019: a pooled analysis of 1201 population-representative studies with 104 million participants. *Lancet*. September 11, 2021;398(10304):957-980.

⁶Coates P, Tuney S, Trudel J, Hettick DA. Time, temperature, power, and impedance considerations for radiofrequency catheter renal denervation. *Cardiovasc Revasc Med*. September 2022;42:171-177.

⁷Mancia G, Kreutz R, Brunstrom M, et al. Authors/Task Force Members: 2023 ESH Guidelines for the management of arterial hypertension The Task Force for the management of arterial hypertension of the European Society of Hypertension Endorsed by the European Renal Association (ERA) and the International Society of Hypertension (ISH). *J Hypertens*. June 21, 2023.

⁸Barbato E, Mahfoud F, et al. Renal denervation in the management of hypertension in adults. A clinical consensus statement of the ESC Council on Hypertension and the European Association of Percutaneous Cardiovascular Interventions (EAPCI). *Eur Heart J*. 2023 Apr 17;44(15):1313-1330

⁹Medtronic data on file. RDN Catheter Historical Data, June 2023. Data includes both Symplicity Flex and Symplicity Spyral.

¹⁰Medtronic Symplicity Spyral™ Instructions for Use.

¹¹Sato Y, Sharp A, Mahfoud F, et al. Translational value of preclinical models for renal denervation: a histological comparison of human versus porcine renal nerve anatomy. *EuroIntervention*. February 6, 2023;18(13):e1120-e1128.

¹²García-Touchard A, Maranillo E, Mompeo B, Sañudo JR. Microdissection of the human renal nervous system : Implications for performing renal denervation procedures. *Hypertension*. October 2020;76(4):1240-1246.

¹³Struthoff H, Lauder L, Hohl M, et al. Histological examination of renal nerve distribution, density, and function in humans. *EuroIntervention*. September 18, 2023;19(7):612-620.

¹⁴Townsend RR, Mahfoud F, Kandzari DE, et al. Catheter-based renal denervation in patients with uncontrolled hypertension in the absence of antihypertensive medications (SPYRAL HTN-OFF MED): a randomised, sham-controlled, proof-of-concept trial. *Lancet*. November 11, 2017;390(10108):2160-2170.

¹⁵Kandzari DE, Böhm M, Mahfoud F, et al. Effect of renal denervation on blood pressure in the presence of antihypertensive drugs: 6-month efficacy and safety results from the SPYRAL HTN-ON MED proof-of-concept randomised trial. *Lancet*. June 9, 2018;391(10137):2346-2355.

¹⁶Symplicity Spyral Renal Denervation System. Sponsor Executive Summary. US FDA Circulatory Systems Devices Panel. Meeting date, August 23, 2023. Pg 121; Figure 58.

¹⁷Medtronic data on file. Global Symplicity Registry clinical data snap, March 2023.



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See the device manual for detailed information regarding the instructions for use, the implant procedure, indications, contraindications, warnings, precautions, and potential adverse events. For further information, contact your local Medtronic representative and/or consult the Medtronic website at medtronic.eu.

For applicable products, consult instructions for use on www.medtronic.com/manuals. Manuals can be viewed using a current version of any major internet browser. For best results, use Adobe Acrobat® Reader with the browser.

For distribution only in markets where the Symplicity Spyral™ multi-electrode renal denervation catheter and Symplicity G3™ renal denervation RF generator have been approved. Not for distribution in the USA, Japan or France.

Learn more



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